UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)))	MDL No. 1456
	)	Civil Action No. 01-CV-12257 PBS
THIS DOCUMENT RELATES TO CLASS 2 & 3 BENCH TRIAL (BMS)	)))	Hon. Patti B. Saris

BMS's MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR TREBLE DAMAGES IN CONNECTION WITH THE CLASS 2/3 TRIAL

Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation ("OTN") and Apothecon, Inc. (collectively, "BMS") respectfully submit this memorandum in opposition to Plaintiffs' Memorandum for an Award of Treble Damages ("Pls. Treble Mem.")

Summary of Argument

BMS adopts and incorporates by reference herein the discussion of the law of multiple damages under Section 9(3) of Chapter 93A in the Memorandum of Defendant AstraZeneca. BMS writes separately to underscore why, on the facts, the assessment of multiple damages against it would be unwarranted. The primary reasons are that (i) the Court's interpretation of the FTC Guides on list prices to require 50% of sales at list is novel, and BMS cannot be said to have engaged in a knowing or willful violation of Chapter 93A based thereon; (ii) as the Court noted in its decision, there was little evidence of BMS "marketing" spread; and (iii) based on HCFA's instructions to Medicare carriers, BMS reasonably believed that the so-called "mega-spreads" on its drugs were part of a ongoing regulatory dialogue between HCFA,

Congress and oncologists on proper reimbursement for overall cancer care, including both drugs and services. We also respond specifically to certain points made by plaintiffs about BMS.

Argument

I. BMS Did Not Engage In a Knowing Or Willful Violation Of FTC Guides

A key basis for the Court's finding of liability against BMS was that BMS did not reduce list prices after its drugs lost exclusivity, even though the average selling price dropped as BMS increased the scope of its discounting to meet generic competition. BMS's fact witnesses and its experts testified that BMS's list price policy was normal profit-maximizing activity for any rational brand drug manufacturer because (1) there were always brand-loyal customers or spot purchasers (*i.e.* those without a contractual entitlement to a discount) who continued to pay the list price and (2) given the volatility of the market, the percentage of sales at list varied from year-to-year (sometimes going up, not down), and it was difficult to predict in advance what would happen. BMS's business model was not a made-for-litigation, post-hoc rationale: it was standard operating practice for branded companies in pharma-economic texts. See Schweitzer, Stuart O., Pharmaceutical Economics and Policy (New York: Oxford Univ. Press 1997) p. 106.

Plaintiffs relied upon several FTC decisions to the effect that a list price could be deceptive or unfair unless "regular" or "usual and customary" sales were made at that price. The FTC Guides Against Deceptive Pricing became an issue because they overruled those decisions[1] and set down the policy that a list price is not fictitious if "substantial" sales are made at that price. The Guides do not assign a specific percentage amount to the word "substantial;" rather, they define substantial as "not isolated or insignificant." 16 C.F.R. § 233.3.

[1] This issue first arose in connection with the parties' summary judgment motions and BMS made it clear that it did not believe that the FTC authorities – which relate to consumer transactions – had any applicability to this case.

In its June 21, 2007 Findings of Fact and Conclusions of Law (the "June 21 Opinion"), the Court found that the case law interpreting the above language from the Guides was "inconclusive." Slip. Op. at 168. The Court went on to hold that BMS's list prices were deceptive or unfair unless more than 50% of net revenues were achieved in sales at or about list. Id. The Court applied this test on a drug-by-drug, year-by-year basis, holding that BMS should have adjusted its list prices as needed to maintain this ratio.

BMS submits that at the time of the conduct at issue in this case – 1997 through 2002 – it could not have reasonably foreseen that its list pricing policies might have violated the FTC Guides, let alone be considered to be deceptive or unfair under Massachusetts law. As the testimony of BMS's expert, Dr. Bell, showed, when all of the BMS drugs subject to generic competition are considered, BMS achieved 31.5% of its net revenues from sales within 5% of list price. (Bell Aff. Ex. E.) BMS would have been justified in believing that this level of sales was not "isolated or insignificant" and that, therefore, its list prices were not deceptive or unfair as a matter of law.

Furthermore, BMS would have been justified in believing that the volatility of the market for its brands after their loss of exclusivity (and the inability to predict in advance how many sales at list might be achieved) entitled it to follow a consistent business model for list prices across all drugs and years. As Dr. Bell's testimony demonstrated, the percentage of net revenue from sales at or about list varied dramatically from year to year – *e.g.*, Vepesid injectible achieved 14.5% of its net revenues from such sales in 1999, but 55.3% in 2000; Cytoxan injectible achieved 6.9% in 2001 but 29.1% in 2002; Rubex achieved 16% in 2000, 62.1% in

2001 and 0% in 2002 when BMS decided to discontinue the product. Obviously, it was difficult to predict in advance the effect on revenues from sales at list.[2]

If BMS were to lower its list prices to reflect what happened in a previous year, it would be limiting the benefit it could achieve from a recovery in a current year. As several witnesses testified, most companies are reluctant to lower their list prices because customers are unwilling to pay more than list price. It would not have been practical for BMS to raise and lower its list prices from year to year.

In short, it would be manifestly unfair to hold BMS liable for multiple damages based on a rule that BMS could not have foreseen and where BMS had reason to believe that it was engaged in legitimate, non-fraudulent pricing activity recognized by standard economic texts.

II. BMS Did Not "Market" Spread

Plaintiffs argue for multiple damages by mischaracterizing this Court's findings on BMS's so-called spread marketing activities. (Pls. Treble Mem. at 10.) In fact, for the drugs in question, the Court found that there was no evidence of any spread marketing other than an OTN "online Cost Differential report for BMS drugs." (Slip. Op. at 74 (citing PX 219); see also id. at 77 (no evidence on Etopophos); 84 (no further evidence on Vepesid); 86 (same as to Cytoxan); 88 (same as to Blenoxane); 89-90 (same on Rubex).) Even there, it is important to note that OTN carried the drugs of all manufacturers (not just BMS) and that the online Cost Differential report was merely a calculator that a customer could and did use with ANY product that it brought through OTN. Thus, the online Cost Differential report cannot be viewed as an

[2] The experience of Taxol after loss of exclusivity was also unusual. Surprisingly, Taxol held its own when generic competition first entered in 2000 (95.3% of net revenues achieved at sales with 5% of list). It also continued to do well in 2001 (41.2%) but then suffered significantly from the intense competition that emerge in 2002 (0.5%). Even in 2002, however, BMS was still able to achieve millions of dollars in sales at list. (See PX-207).

effort to market BMS drugs over another company's drugs. (Akscin Aff. ¶¶ 10, 12-13, 20; Akscin 12/06/06 Tr. 62-68; Peterson Aff. ¶¶ 7-9, 14, 16.)

As to the two drugs for which the Court did find evidence of actual spread marketing by BMS or OTN sales representatives, plaintiffs ignore the following evidence:

- BMS's written policy against its salespersons' marketing or promoting its drugs based on spread allowed them to respond to concerns voiced by providers. (The BMS Defendants' Post-Trial Proposed Findings of Fact ("BMS Findings") ¶ 27.))

- A search of the sales representatives' "call notes" with doctors reveals that fewer than ½ of 1% of over 80 million computer records reflect any discussion of reimbursement, discounts spreads or similar concepts. (BMS Findings ¶ 29.)

- The uncontradicted testimony at trial and in deposition was that those few discussions that did occur on those subjects were almost always brought on by inquiries from the providers who threatened to switch to a generic version of the BMS drug. (BMS Findings ¶¶ 28, 41 & n.10.)

- Because neither the doctor nor the BMS sales representative had any ability to negotiate price, all a representative could do was illustrate to a provider the extent to which the BMS drug remained competitive with the generic. Any AWP and spread information made available by the BMS or OTN representatives to individual physicians was purely factual and could not be changed to "make" a sale of a BMS drug. (BMS Findings ¶¶ 30, 33.)

- The "Practice Efficiencies" document upon which plaintiffs relied so heavily at trial did not compare spreads on BMS drugs to those of any other manufacturer, it contained only general information about AWP-based reimbursement and was used by one sales representative in only "one or two instances." (BMS Findings ¶¶ 43-44.)

For all these reasons, the evidence (or more accurately, the lack thereof) with respect to BMS's spread marketing militates against the imposition of multiple damages.

III. <u>BMS Reasonably Believed That HCFA Knew Of "Mega Spreads"</u>

Throughout this litigation, plaintiffs have focused on "mega-spreads." It is clear, however, that the BMS drugs for which the Court found "mega-spreads" were the express subject of government reports and news media articles going back at least to 1992. Thus, BMS

had reason to believe that the government and TPPs knew of mega-spreads on its particular multi-source drugs -- Vepesid (etoposide), Cytoxan (cyclophosphamide), Blenoxane (bleomycin) and Rubex (doxorubicin hcl) -- from OIG and Congressional reports, the Barron's "Hooked On Drugs" article and several other sources.

Most importantly, in 2000 HCFA considered using lower, more "accurate" AWPs to eliminate mega-spreads, but soon withdrew the idea and instructed its carriers to continue using published AWPs for cancer drugs. HCFA made this decision on reimbursement for the drugs themselves because, "Medicare payments related to the *provision* of chemotherapy drugs . . . are inadequate." (June 21 Opinion at 19 (citing DX 1090 at 0059); see also DX 1091 (Program Memorandum for Medicare Carriers (italics added)).) The Court noted that HCFA took this position as a result of pressure from members of Congress, who in turn were receiving pressure from doctors and patient advocacy groups. (Id. at 32.) It would not have made sense, under these circumstances, for BMS to frustrate HCFA's decision by unilaterally lowering reduced the spreads for its drugs.

Indeed, as Dr. Berndt pointed out, it would not have been possible for any manufacturer, at any time, to take unilateral action to reform the AWP system. HCFA and Congress set up a system where doctors could make money on drug spreads. Spreads were the result of discounting, which occurred when a manufacturer faced therapeutic or generic competition. It is not in the interest of any manufacturer to have a spread exceeding 30% unless its competitor is offering a spread in excess of 30%. If BMS had taken steps to ensure that it never had spreads in excess of 30%, it would have gone out of business.

We understand that the Court has already decided that the inability of any manufacturer to take unilateral action is not an excuse, but the decision of manufacturers to

continue to compete within the constraints of a system created by others is hardly evidence of willfulness.

Conclusion

For all the foregoing reasons, BMS respectfully submits that Plaintiffs' request for multiple damages be denied.

Dated: August 6, 2007

Respectfully Submitted,

/s/ Thomas E. Dwyer (BBO No. 139660)

DWYER & COLLORA, LLP
Thomas E. Dwyer (BBO No. 139660)
Jennifer M. Ryan (BBO No. 661498)
600 Atlantic Avenue
Boston, MA 02210
Tel: (617) 371-1000
Fax: (617) 371-1037
tdwyer@dwyercollora.com
jryan@dwyercollora.com

Steven M. Edwards (SE 2773)
Lyndon M. Tretter (LT 4031)
Thomas J. Sweeney, III (TS 6557)
Admitted *pro hac vice*
HOGAN & HARTSON LLP
875 Third Avenue
New York, NY 10022
Tel: (212) 918- 3000

Attorneys for Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation and Apothecon, Inc.

CERTIFICATE OF SERVICE BY LEXIS-NEXIS FILE & SERVE

I, Lyndon M. Tretter, hereby certify that I am one of Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp.'s attorneys and that, on August 6, 2007, I caused a copy of **BMS's MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR TREBLE DAMAGES IN CONNECTION WITH THE CLASS 2/3 TRIAL** to be served on all counsel of record by electronic service pursuant to Paragraph 11 of CMO No. 2 by sending a copy to Lexis-Nexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter
Lyndon M. Tretter